

### **REMARKS**

Claims 1-23 are pending, wherein claims 1-2, 4-9, 11, 13-15 and 17-23 have been amended. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks.

The present invention relates to a suture pulley assembly that includes a rotatable pulley wheel which is able to equalize tension on both sides of a looped suture and that is able to spread apart or collapse in response to changes in suture width. The suture pulley assembly includes means for rotatably attaching a side of the pulley wheel to an adjustable tension applicator of a graft tensioning device in order for the rotatable pulley wheel to transmit varying tensile loads from the adjustable tension applicator to the looped suture.

In another embodiment, a graft tensioning device is provided that includes a suture pulley assembly attached to at least one adjustable tension applicator, wherein the suture pulley assembly is positioned so as to move together with the adjustable tension applicator in order to transmit a desired tensile load from the adjustable applicator through the suture pulley assembly to a looped suture wrapped around the pulley wheel within the pulley space and attached to free ends of a looped tissue graft. The cited art neither teaches nor suggests any such suture pulley assembly or graft tensioning device.

The Office Action rejects claims 1-8 and 11-22 under 35 U.S.C. § 112, second paragraph, as being indefinite with respect to how the preambles of claims 1 and 11 were previously written. Applicants state for the record that a Jepson style claim was not intended. Therefore, Applicants have amended claims 1 and 11 in order to remove the alleged ambiguity. Applicants therefore respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, in view of the foregoing amendment.

The Office Action rejects claims 1-23 under 35 U.S.C. § 103(a) as being unpatentable over Lewis et al. (U.S. Patent Number 4,950,271) in view of Fletcher (U.S. Patent Number 3,869,932). While Applicants reassert their previous position that one of skill in the art could not have combined Lewis et al. with Fletcher to obtain the combination of elements recited in the claims as previously presented without the use of improper hindsight (in violation of *KSR* and *Graham v. John Deere*), Applicants have amended the claims in order to further clarify aspects that more clearly distinguish over the combination of Lewis et al. and Fletcher.

Claim 1 as amended claims a suture pulley assembly comprising a rotatable pulley wheel, attaching means for rotatably attaching only one side of the pulley wheel to an adjustable

tension applicator so that an outer perimeter of each of the first and second pulley plates of the pulley wheel and also the pulley space remain entirely unobstructed by any structure of the graft tensioning device in order to provide free and unobstructed access of a looped suture with no free end around the pulley wheel within said pulley space, and biasing means for biasing at least one of said pulley plates toward the other with a biasing force in order for the pulley space to selectively increase or decrease in cross-sectional width in response to the insertion of differently sized sutures into the pulley space. Support for the amendments to claim 1 are clearly shown in Figures 1 and 6.

Claim 1 as amended is neither taught nor suggested by the applied art. For example, Lewis et al. neither teaches nor suggests any attaching means for rotatably attaching only one side of the pulley wheel to an adjustable tension applicator. As clearly shown in Figure 2 of Lewis et al., the axel passing through the hole of pulley 57 is attached at both sides to bracket 56 of the "fixture" 40. That is most easily seen in the middle one of the three legs of "fixture" 40 shown in Figure 2. As shown in Figure 2 of Lewis et al., the perimeter of both pulley plates of the "guide pulley" 57 and also the pulley space are partially surrounded by bracket 56. As a result, it would be impossible to place a looped suture with no free end around the "guide pulley" 57 of Lewis et al., as bracket 56 would block any such attempt to place a looped suture around "guide pulley" 57. In contrast, claim 1 as amended requires that the outer perimeter of each of the first and second pulley plates and also the pulley space remain entirely unobstructed by any structure of the graft tensioning device in order to provide free and unobstructed access of a looped suture with no free end around said pulley wheel within said pulley space. For this reason alone, Lewis et al. neither teaches nor suggests the attaching means recited in claim 1. Fletcher has nothing to do with the claimed suture pulley assembly and likewise fails to teach or suggest any such attaching means.

Lewis et al. also fails to disclose attaching means for rotatably attaching the pulley wheel to an adjustable tension applicator of the graft tensioning device. The tension applicator, to the extent one is present in Lewis et al., consists of elements 62 (a load cell) and 64 (clamp), which are able to move relative to the length adjusting assembly 50. The guide pulley 57, however, is not in any way attached to the movable tension applicator 62/64 but rather to the *immobile* bracket/flange 56, which remains stationary while the tension applicator 62/64 is adjusted to apply varying tensile loads. As a result, Lewis et al. provides no means at all for connecting the guide pulley 57 to the tension applicator 62/64. Moreover, it would be contrary to Lewis et al. to

provide such connection means. For this additional reason, Lewis et al. neither teaches nor suggests the attaching means recited in claim 1. Fletcher is even more deficient as it has nothing to do with a suture pulley assembly.

In addition, the Office Action admits that Lewis et al. fails to teach or suggest any biasing means for biasing at least one of the pulley plates toward the other pulley plate. For this reason the Office Action attempts to combine Fletcher with Lewis et al. However, Fletcher involves a "variable drive pulley" for use with a relatively large electric motor. Col. 1, line 7; col. 3, lines 12-13. The Fletcher device includes leaf springs H having sufficient force to urge pulley plates 60 and 62 together with sufficient force to maintain a belt F in a clamped position therebetween in order to transmit force from the electric motor to the belt F. The amount of force required to maintain a belt F in the required pinched position is undoubtedly many magnitudes greater than the force exerted by the biasing means in the suture pulley assembly of claim 1, which, as amended, exerts a biasing force such that the pulley space will selectively increase or decrease in cross-sectional width in response to insertion of differently sized sutures in the pulley space. Applicants submit that the biasing force shown in Fletcher is inherently so great as to not permit a pulley space to selectively increase or decrease in response to differently sized sutures. On the other hand, neither Lewis et al. nor Fletcher suggest the desirability of modifying the biasing force to achieve the result recited in claim 1. For this additional claim 1 is patentable over the combination of Lewis et al. and Fletcher.

Dependent claims 2-10 define additional limitations that further distinguish over the cited art. For example, claim 2 further requires that the second end of the post opposite the first end remains unattached to any portion of the adjustable tension applicator, as shown in Figure 1 of the present application. In contrast, Figure 2 of Lewis et al. clearly shows that both ends of the post passing through guide pulley 57 are attached to flange 56 of the Lewis et al. device. Fletcher, on the other hand, has absolutely nothing to do with attaching an end of a suture pulley wheel to an adjustable tension applicator.

Claim 4 further recites that the post includes a flange at the second end, with the flange remaining unattached to any portion of the adjustable tension applicator so that it cannot obstruct the outer perimeter of each of said first and second pulley plates or said pulley space. This permits unobstructed access to the pulley space of a looped suture with no free ends. In sharp contrast, Figure 2 of Lewis et al. shows that the both sides of flange 56 on both sides of guide pulley 57 are rigidly attached to the remaining portion of the Lewis et al. device. For this reason

it would be impossible to attach a looped suture with no free ends around the pulley 57 of Lewis et al.

Dependent claim 5 further claims that the biasing means comprises a spring axially positioned around a portion of the post, as shown in Figure 6 of the present application. Lewis et al. admittedly includes no such spring. The leaf springs H of Fletcher are not axially disposed around a portion of any post as clearly seen in Figure 2 of Fletcher (*i.e.*, they are radially disposed in a spoke-like fashion).

Claim 6 further specifies that the spring comprises a coiled spring axially positioned around the post, as shown in Figure 6 of the present application. Neither Lewis et al. nor Fletcher disclose any coiled spring, let alone one having a position relative to a post as recited in claim 6.

Claims 7 and 8 recite that first and second pulley plates are rotatably attached to a post and are able to spread apart axially relative to each other along an axis of the post. The Office Action admits that the pulley plates of pulley 57 of Lewis et al. are fixed and are therefore unable to move together or apart relative to each other. Fletcher, on the other hand, does not disclose pulley plates that are rotatably attached to a post but which are rather rigidly clamped to the post so as to turn along with the post. Accordingly, claims 7 and 8 further distinguish over combined teachings of Lewis et al. and Fletcher.

Claim 9 recites a graft tensioning device that includes the suture pulley assembly of claim 1 and at least one adjustable tension applicator to which the pulley wheel of the suture pulley assembly is rotatably attached, wherein the suture pulley assembly is configured to move together with said adjustable tension applicator in order to transmit a desired tensile load from said adjustable tension applicator through said suture pulley assembly to a looped suture wrapped around said pulley wheel within said pulley space and attached to free ends of a looped tissue graft. Support for this amendment is shown in Figures 2 and 2A of the present application. As discussed above, the "guide pulley" 57 of Lewis et al. is attached to the nonmovable bracket 56 rather than to the movable tension applicator 62/64. As a result, Lewis et al. neither teaches nor suggests any graft tensioning device in which the pulley wheel assembly is able to move together with an adjustable tension applicator in order to transmit tensile load from the tension applicator through the pulley assembly to a looped suture. Instead, the "guide pulley" 57 merely acts passively to guide the position of the suture but that does not move together with tension applicator 62/64, nor does it transmit any tensile load.

Independent claim 11 is similar to independent claim 1, but further recites a post attached at a first end, with a second end remaining unattached to any portion of the adjustable tension applicator, and a spring axially disposed around a portion of the post. As discussed above, the post of Lewis et al. through guide pulley 57 is attached at both ends of the bracket/flange 56, as clearly shown in Figure 2 of Lewis et al. Moreover, Lewis et al. neither teaches nor suggests a spring axially disposed around a portion of a post. Nor does Fletcher disclose any such spring but rather leaf springs H which radiate outward in a spoke-like fashion from a central axis as clearly shown in Figure 2 of Fletcher. Accordingly, Applicants submit that claim 11 is patentable over the combination of Lewis et al. and Fletcher.

Dependent claims 12-22 include additional limitations that further distinguish over the applied art. For example, claim 14 claims that a portion of the inner surfaces of the first and second pulley plates are angled so that a portion of the pulley space has decreasing width from the outer perimeter and so that a portion of the pulley space nearest the center of the pulley wheel has a constant width, as shown in Figure 6 of the present application. In contrast, the pulley plates of Fletcher are angled along their entire length so that they do not define any portion having constant pulley space width. Nor does Lewis et al. teach or suggest any such configuration.

Claim 15 requires the spring to have a biasing force in order for the first and second pulley plates to spread apart in response to inserting a suture having a knot or half knot into the pulley space. Lewis et al. admittedly does not include pulley plates that are able to move apart at all. Fletcher, in contrast, discloses a pulley for use with an electric motor that has sufficient clamping force to clamp a drive belt therebetween with sufficient force to prevent slippage of the drive belt. Accordingly, neither Lewis et al. nor Fletcher teach or suggest a spring having a biasing force of the magnitude as recited in claim 15.

Claim 17 further claims a flange that remains unattached to any portion of the adjustable tension application so as to not obstruct the outer perimeter of each of said first and second pulley plates or said pulley space. In contrast as shown in Figure 2 of Lewis et al., the alleged "flange" 56 is in reality described in Lewis et al. as a "bracket" and is rigidly attached to the main body of the "fixture" 40 shown in Figure 2 and therefore obstructs both the outer perimeter of both of said first and second pulley plates and the pulley space.

Claims 18 and 19 further claim a coiled spring axially positioned around the post. Neither Lewis et al. nor Fletcher teach or suggest a coiled spring of any kind, let alone that is axially positioned around a pulley post.

Claim 20 further recites a sleeve axially disposed around at least a portion of the post. No such sleeve is shown in either Lewis et al. or Fletcher. Nor does the Office Action even allege that they do such that claim 20 is not *prima facie* obvious over these references. As a result, claim 21 is also not *prima facie* obvious over the applied art.

Claim 22 further claims a washer that is axially disposed around the post. The Office Action did not even allege that Fletcher or Lewis et al. disclose any such washer. Accordingly, claim 22 is not *prima facie* obvious over the applied art.

Finally, claim 23 claims a graft tensioning device that includes at least one movable adjustable tension applicator and a suture pulley assembly attached to the movable adjustable tension applicator and that is movable together with the adjustable tension applicator so as to transmit varying tensile loads from the adjustable tension applicator to the looped suture as said adjustable tension applicator is moved relative to the looped suture. This is demonstrated by comparing Figures 2 and 2A, which show varying positions of the adjustable tension applicator and the suture pulley assembly moving together with the adjustable tension applicator. In sharp contrast, the guide pulley 57 of the Lewis et al. is attached to the non-movable "bracket" 56 of "fixture" 40 and therefore remains stationary even though the tension applicator 62/64 can be moved in and out relative to a suture to apply varying tensile loads. Accordingly, Applicants submit that claim 23 is patentable over the combination of Lewis et al. and Fletcher.

In view of the foregoing, Applicants submit that the application is in allowable condition. In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 9<sup>th</sup> day of November 2007.

Respectfully submitted,



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